Clinicopathological evaluation of radical retropubic prostatectomy-positive outcome even at institutes with relatively limited experience

AUTHOR(S):

Okamura, Takehiko; Akita, Hidetoshi; Tozawa, Keiichi; Kohri, Kenjiro

CITATION:

Okamura, Takehiko ...[et al]. Clinicopathological evaluation of radical retropubic prostatectomy-positive outcome even at institutes with relatively limited experience. 泌尿器科紀要 2007, 53(8): 533-537

ISSUE DATE:

2007-08

URL:

http://hdl.handle.net/2433/71469

CLINICOPATHOLOGICAL EVALUATION OF RADICAL RETROPUBIC PROSTATECTOMY-POSITIVE OUTCOME EVEN AT INSTITUTES WITH RELATIVELY LIMITED EXPERIENCE

Takehiko Okamura[1], Hidetoshi Akita[1], Keiichi Tozawa[2] and Kenjiro Kohri[2]

[1]*The Department of Urology, Anjo Kosei Hospital*

[2]*The Department of Nephro-Urology, Nagoya City University Graduate School of Medical Sciences*

A total of 161 patients underwent radical retropubic prostatectomy at our 11 institutions in the three-year period from January 2001 to December 2003. The numbers per institution ranged from 1–36, with 5 institutions conducting 20 or more (131 cases), and 6 performing less than 15 (30 cases). Here we examined the differences in operation parameters and patient outcome between these two groups. Time for surgery, associated loss of blood, lymphadenectomy, preservation of neurovascular bundles, time for removal of indwelling catheters, post-operation complications, and subsequent urinary incontinence, were assessed. There were no differences between the two groups of hospitals, except with regard to surgery time and incontinence, where the period to 'pad-free' was an average of more than 40 days longer in institutions undertaking only a small number of operations. From our experience with radical retropubic prostatectomy, series of hospitals, there is no reduction in safety with such intervention performed by institutions undertaking only a small number of operations.

(Hinyokika Kiyo **53** : 533–537, 2007)

Key words : Radical retropubic prostatectomy, Retrospective study, Limited experience, Positive outcome

INTRODUCTION

Due to progress in methodology and anatomical understanding, radical retropubic prostatectomy for early prostate cancers is now feasible in almost all hospitals. With improvements in laparoscopy, the success rate without the need for open surgery has increased. However, the Ministry of Health, Labour and Welfare of Japan for a period of time decided health coverage should not totally be made available for radical retropubic prostatectomy in institutions in which only a small number of operations are performed. This, together with the natural trend for patients to select larger hospitals, meant that nearly all operations were performed in large institutions, for example, with the necessary equipment for laparoscopy. However, our group has long questioned whether this was the most appropriate policy, given the large number of hospitals with limited experience and therefore the likelihood that only a few surgeons would actually be able to maintain their ability to effectively conduct radical retropubic prostatectomy.

Numerous reports have documented a volume-outcome relationship for complex treatments[1–4] and in one review of 70 studies, over 60 demonstrated significantly better results with high volume hospitals[5,6]. In the urological field, there have been many similar reports with regard to radical retropubic prostatectomy[7–9]. Although outcome will depend on the difficulty of the contemplated surgery and with radical retropubic prostatectomy, it has been shown that performance at non-academic institutions can give outcomes equivalent to those experienced at teaching hospitals[10]. Since this is a very important question of priority, we therefore conducted the present retrospective study of cases in our group of hospitals, all of which had at least 150 beds and well-equipped surgical facilities, focusing on surgical procedures and complications as well as longer-term results. Special attention was devoted to incontinence, since this is a major problem with radical retropubic prostatectomy[11–14].

PATIENTS AND METHODS

A total of 161 patients underwent radical retropubic prostatectomy at our 11 institutions in the three-year period from January 2001 to December 2003. All of the hospitals were selected on the basis of having at least 150 beds, good surgical facilities and access to outside surgeon assistance. The period was arbitrarily chosen. The numbers per institution ranged from 1–36, with 5 institutions conducting 20 or more (131 cases ; group 1), and 6 performing 14 or less (30 cases ; group 2). The numbers of cases in each institution are summarized in Table 1. In order to increase the likelihood of observing as statistically significant difference, comparison was made between hospitals with 1–14 cases and those with more than 19 cases, the institutes performing 15–19 cases being excluded from the analysis for this purpose. Age at surgery, post-surgical hospital stay, follow-up period after surgery, biopsy results and post surgical pathology,

Table 1. Number of radical retropubic prostatectomy cases at each institution

Group 1	
Hospital A	36
Hospital B	29
Hospital C	25
Hospital D	21
Hospital E	20
Total	131
Group 2	
Hospital F	12
Hospital G	8
Hospital H	4
Hospital I	3
Hospital J	2
Hospital K	1
Total	30

conditions of neoadjuvant therapy, radiation therapy, post surgical PSA elevation and its interval were compared between the groups, along with time for surgery, associated loss of blood, lymphadenectomy, preservation of neurovascular bundles, time for removal of indwelling catheters, post-surgical complications, and subsequent urinary incontinence. Regarding urinary incontinence, the treating physician evaluated the outcomes by patient questionnaires at each visit. The criterion for no urinary incontinence was determined as absolutely no leakage during the entire day so that the patients were pad free.

Surgically removed specimens were routinely fixed in 10% buffered formalin, embedded in paraffin, sectioned and stained with hematoxylin and eosin. Tumor grading, staging, and assessment of pathological efficacy of hormonal therapy were performed in accordance with the 3rd edition of the "General Rules for Clinical and Pathological Studies on Prostate Cancer of the Japanese Urological Association and The Japanese Society of Pathology". Histopathological diagnoses of pre and post surgical staging were also compared for the two groups. Statistical analyses were performed using the Welch's t-Test and Wilcoxon's Rank-Sum Test with the statistical software package EXEL Statistics Ver 5.0 (ESUMI Co., Ltd., Tokyo, Japan). A value of $p<0.05$ was considered as statistically significant.

RESULTS

Comparisons of post-surgical hospital stay and follow-up period after the surgery for the two groups showed no significant differences, although the age at surgery was significantly younger (more than 2 years) in group 1 ($p=0.024$), as shown in Fig. 1. Up to 20% of cases lacked data for each category (especially lymphadenectomy and nerve sparing), but statistical comparison between the two groups proved possible in all cases. Biopsy results

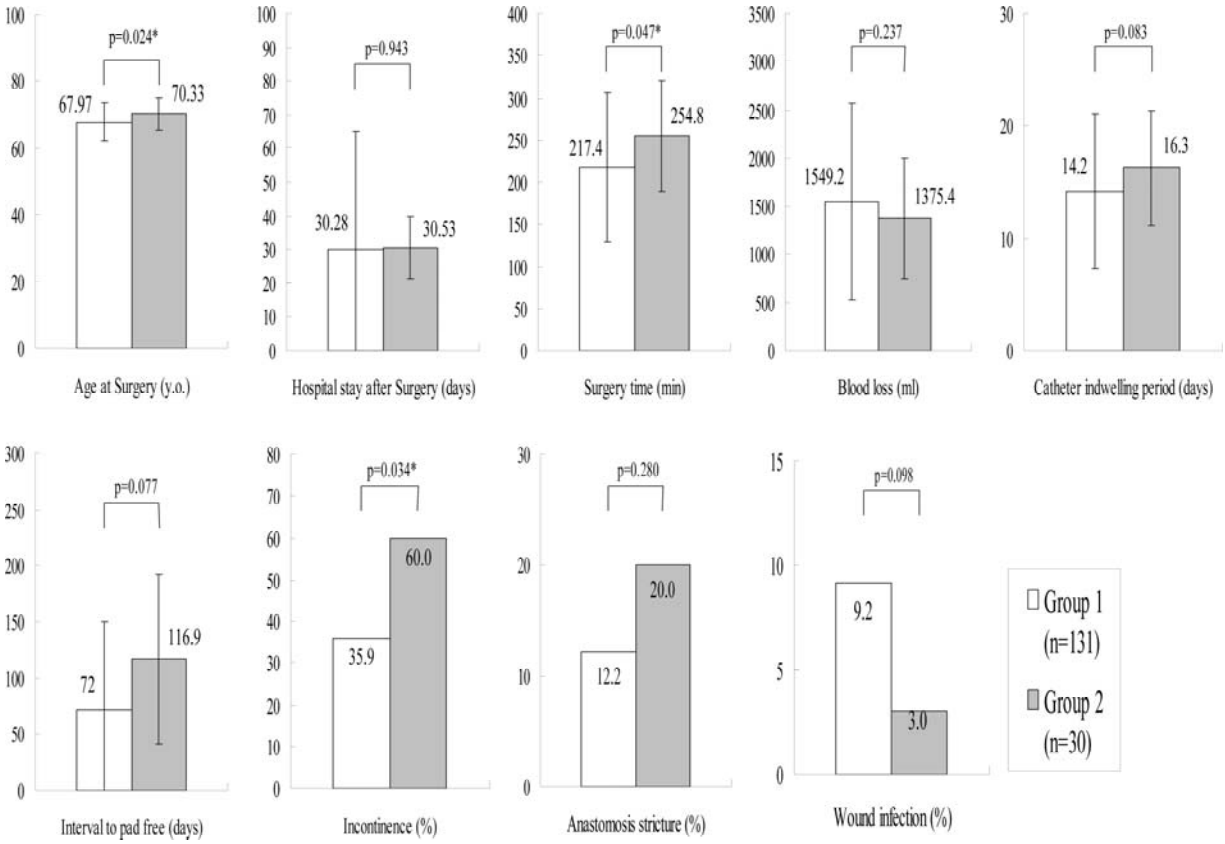

Fig. 1. Comparison of surgery parameters between the two groups. Asterisks indicate significant differences between the two groups.

before surgery and post-surgical pathology were essentially the same results in both groups. Neoadjuvant therapy were performed in 99 patients of group 1 (3.7±4.7 months), and 24 of group 2 (5.5±12.1 months). Radiation therapy after surgery was conducted in only 3 patients of group 1 and 6 of group 2. Post surgical PSA elevation was experienced in 9 cases in group 1 (10.8±6.5 months) and 4 in group 2 (13.3±5.4 months). None of these demonstrated significant inter-group differences.

Only 11 cases in group 1 and 5 in group 2 underwent nerve sparing surgery, but again there was no significant difference between the two groups ($p=0.060$). While the average catheter indwelling period was almost the same, the maximum period was almost 2 times longer in group 1 (50 days).

More than 30% of group 1 and 60% of group 2 remained incontinent at the end of follow-up period ($p=0.034$). Regarding the time until 'pad free', the institutions undertaking only a small number of operations showed an average increase of more than one month, but this difference was not significant ($p=0.077$). All these data are shown in Fig. 1.

Pathological analysis of the removed prostate tissue demonstrated no significant variation in tumor differentiation and stage. Margin positive cases which could be evaluated were 45.8% (54 of 118) in group 1, and 63.0% (17 of 27) in group 2, and this difference also being no significant finding ($p=0.107$). Furthermore there were no significant differences in neoadjuvant therapy, post-surgical radiation therapy and PSA elevation.

DISCUSSION

The present study provided clear evidence that surgical complications and longer-term outcome, in fact do not differ with numbers of radical retropubic prostatectomy performed at institutions undertaking such surgery only rarely or relatively infrequently in our group of hospitals. According to parameters of morbidity such as blood loss (1,364±1,011 ml vs 1,549 ±1,018 ml in group 1, and 1,375±627 ml in group 2), or wound infection (7.5% vs 9.2% in group 1, and 3.0% in group 2) our results were similar to those reported earlier for frequent case hospitals in Japan[15].

The one exception concerning length of time until a pad-free state was achieved, while statistically significant, clearly does not have the same major clinical importance as recurrence of cancer. Moreover, observation period for our cases was relatively short to determine the pad free and incontinence rates, ranging from only 198 to 1,303 days (average 675 days : less than 2 years). Younger patients tend to recover urinary continence earlier than older counterparts[11] and therefore the fact that the average age was more than 2 years younger in group 1, with significance, could partly explain the observed difference between the two groups. Litwin et al. in fact reported that urinary incontinence after radical retropubic prostatectomy decreased only gradually even over a period of 3 years[11] and Penson et al. also described continued improvement after 2 years[14]. It should be borne in mind that Krupski et al. demonstrated variation in continence results after radical retropubic prostatectomy depending on the specific definition used[16]. However, our definition of continence was very strict. Many criteria may be included so that it is relatively difficult to compare the pad-free period between our two groups and a more exhaustive re-evaluation may be needed in the future.

As noted in the introduction, there have been numerous reports concerning the general volume outcome relationship of hospitals and surgeons[1–4], but one in particular described comparable results between academic and nonacademic institutions[10]. While most studies of radical cystectomy or prostatectomy in the United States showed benefits of larger volume facilities[17,18] there may be differences in patient characteristics between countries, like level of obesity, which could play a role. Bianco et al. reported that morbidity or outcomes of high volume hospitals or surgeons can also show significant variation[19]. Clearly there are many factors which can have an impact and complications or morbidity associated with surgery is not only determined by hospital volume, but also the individual surgeon's experience, the available surgical equipment, and skill of paramedical staff. To evaluate exact outcome, the entire environment must be considered, covering assistant surgeons' skill, educational elements, and other parameters influencing the environment in the operating room.

In this context, we would like to draw attention to the frequent changing of surgeons among our concerned hospitals. Almost all small institutions have staff who earlier gained experience in larger teaching hospitals. Indeed this was the case with all of the hospitals participating in the present study. Their urologists all graduated from or received training at Nagoya City University. If there were no skilled urologists in hospitals undertaking very few operations, our concerned hospitals had the supporting system of calling out for help on the operation day. Furthermore, the quality of paramedical staff training is also given great emphasis in Japan, independent of the size of the hospital. Therefore the results of the present study, showing that radical retropubic prostatectomy can be performed even in hospitals undertaking very few cases, are totally in line with expectation. We believe that the Ministry of Health, Labour and Welfare of Japan was correct in reconsidering its decision to provide health coverage for radical retropubic prostatectomy only in institutions in which many operations are performed. Taking into account the continued increase in incidence rates for prostate cancer and related surgery in Japan[15] it is essential that we have sufficient facilities and

surgical expertise to cope with increments in demand for radical retropubic prostatectomy in the future.

CONCLUSION

From our experience with radical retropubic prostatectomy in a group of 11 hospitals, all having over 150 beds and up-to-date facilities within the Nagoya City University orbit, there is no reduction in safety with surgery performed by institutions undertaking only small numbers of operations.

REFERENCES

1) Shahian DM and Normand ST : The volume-outcome relationship : from Luft to Leapfrog. Ann Thorac Surg **75** : 1048–1058, 2003
2) Sowden AJ, Deeks JJ and Sheldon TA : Volume and outcome in coronary artery bypass graft surgery : true association or artefact ? BMJ **311** : 151–155, 1995
3) Begg CB, Cramer LD, Hoskins WJ, et al. : Impact of hospital volume on operative mortality for major cancer surgery. JAMA **280** : 1747–1751, 1998
4) Finlayson EV, Goodney PP and Birkmeyer JD : Hospital. volume and operative mortality in cancer surgery. Arch Surg **138** : 721–725, 2003
5) Dudley RA, Johansen KL, Brand R, et al. : Selective referral to high-volume hospitals : estimating potentially avoidable deaths. JAMA **283** : 1159–1166, 2000
6) Dudley RA and Johansen KL : Invited commentary : physician responses to purchaser quality initiatives for surgical procedures. Surgery **130** : 425–428, 2001
7) Begg CB, Riedel ER, Bach PB, et al. : Variations in morbidity after radical prostatectomy. N Engl J Med **346** : 1138–1144, 2002
8) Hu JC, Gold KF, Pashos CL, et al. : Role of surgeon volume in radical prostatectorny outcomes. J Clin Oncol **21** : 401–405, 2003
9) Ellison LM, Heaney JA and Birkmeyer JD : The effect of hospital volume on mortality and resource use after radical prostatectomy. J Urol **163** : 867–869, 2000
10) Cohn JH and El-Galley R : Radical prostatectomy in a community practice. J Urol **167** : 224–228, 2002
11) Litwin MS, Melmed GY and Nakazon T : Life after radical prostatectomy : a longitudinal study. J Urol **166** : 587–592, 2001
12) Cooperberg MR, Master V and Carrol PR : Health related quality of life significance of single pad urinary incontinence following radical prostatectomy. J Urol **170** : 512–515, 2003
13) Namiki S, Kuwahara M, Ioritani N, et al. : An evaluation of urinary function after radical prostatectomy in Japanese men : concordance with definitions of urinary continence. BJU Int **95** : 530–533, 2005
14) Penson DF, McLerran D, Feng Z, et al. : 5-year urinary and sexual outcomes after radical prostatectomy : results reom the prostate cancer outcomes study. J Urol **173** : 1701–1705, 2005
15) Arai Y, Egawa S, Tobisu K, et al. : Radical retropubic prostatectomy. time trends, morbidity and mortality in Japan. BJU Int **85** : 287–294, 2000
16) Krupski TL, Saigal CS and Litwin MS : Variation in continence and potency by definition. J Urol **170** : 1291–1294, 2003
17) Nuttall M, van der Meulen J, Phillips N, et al. : A systematic review and critique of the literature relating hospital or surgeon volume to health outcomes for 3 urologicalcancer procedures. J Urol **172** : 2145–2152, 2004
18) Konety BR, Dhawan V, Allareddy V, et al. : Inpact of hospital and surgeon volume on in-hospital mortality from radical cystectomy : data from the health care utilization project. J Urol **173** : 1695–1700, 2005
19) Bianco Jr FJ, Riedel ER, Begg CB, et al. : Variations among high volume surgeons in the rate of complications after radical prostatectomy : further evidence that technique matters. J Urol **173** : 2099–2103, 2005

(Received on April 6, 2006
Accepted on February 21, 2007)

和文抄録

根治的前立腺全摘例の臨床病理学的検討
—少数例施設の妥当性—

岡村　武彦[1]，秋田　英俊[1]，戸澤　啓一[2]，郡　健二郎[2]
[1]安城更生病院，[2]名古屋市立大学大学院医学研究科腎・泌尿器科学分野

われわれの関連病院における，根治的前立腺全摘例での少数例施設の妥当性についてレトロスペクティブに検討した．

2001年１月から2003年12月までの３年間に施行した11施設，161例の根治的前立腺全摘例を対象とした．１施設あたりの症例数は１例から36例で，20症例以上の５施設131例と，14例以下の６施設30症例で２群間での比較検討を行った．

手術時間，出血量，リンパ節郭清の有無，神経温存の有無，カテーテル留置期間，術後合併症，術後尿失禁の状態について検討した．その結果，手術時間の有意な延長と，パットフリーになるまでの期間が少数例の施設において平均で40日以上長くかかった．他のすべての項目においては有意な差はなかった．

以上の結果から，われわれの関連病院における根治的前立腺全摘術は，少数例の施設においては術後尿失禁の程度はやや劣るものの，安全に施行されていることが示唆された．

（泌尿紀要 **53**：533-537，2007）

EDITORIAL COMMENT

厚生労働省が前立腺全摘術に対する保険請求金額に年間の前立腺全摘手術件数により差をつける（少数件数しか行っていない施設は70％に請求額が抑制される）ことに対して，本論文はその件数での格差付けに異議を唱えるものである．

厚生労働省の意図が①慈恵医科大学・青戸病院での内視鏡下前立腺全摘術の無謀な医療行為に対する警鐘，あるいは②医療費抑制政策の一法，にあるのか定かでない．しかし，新たな秩序を築こうとすると，必ず一方で新たな混乱あるいは混沌が生ずることも危惧される．この例でいえば，この危惧は，小都市において前立腺全摘術を行うのは困難になり，患者は自己の住居地から離れた遠隔の大都市での手術を受けることを余儀なくさせられるという混乱，などである．

田舎，過疎地での医療事情を知るものとして，本論文の意図した「手術件数だけで分類しても，多い手術件数を行っている・大医療機関群と小数しか行わなかった小医療機関群との２群間で手術に関する種々パラメーターで明らかな差はなかった．よって…件数だけでの差別化は意味がないのでは…」とすることを提示したことは重要と思われるし，厚生労働省の政策に対して，反論ともなり得るものである．

しかし，科学論文として評価を行うならば，手術件数という大雑把な因子を用いたことが（厚生省に対しての反論である以上致し方ない部分があるが）結論を明確化できえなかった原因となっている．なぜなら，この研究対象地域に非常に元気な先生と元気な前立腺全摘チームが存在して，同一の医師群が研究対象の11施設で行われたすべての全摘術を行ったのであれば，手術件数によって結果に差が生じないことに，同意は容易にできる．もし，この条件下で差が出るようならば看護士らの術者以外の因子が重要となり，その追求を行うべきである．本論文では，残念ながら，術者集団の細かい解析や検討を行っていない．よって，「手術件数という経験は治療成績に貢献するはずである．」という一般常識に反するかのような誤解を与える危険性を含む論文となってしまったことが残念である．

伊豆高原クリニック　今　井　強　一